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FROM: Gina N. Shishima**FLOOR:** 20**PHONE:** (512) 536-3081**FAX:** (512) 536-4598**RE:** Serial No. 10/593,202**NUMBER OF PAGES INCLUDING COVER PAGE:****MESSAGE:****Examiner Wilson,**

Please find attached DRAFT claim Amendments for your review and discussion during the interview scheduled today, September 2, at 2:00 p.m. (EST).

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Gina Shishima

DRAFT**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Larry R. Rohrschneider

Serial No.: 10/593,202

Filed: July 25, 2007

For: METHODS AND COMPOSITIONS
INVOLVING S-SHIP PROMOTER
REGIONS

Group Art Unit: 1632

Examiner: Wilson, Michael C.

Atty. Dkt. No.: FHCC:016US

Confirmation No.: 5927

DRAFT AMENDMENT TO OFFICE ACTION
DATED JUNE 23, 2010Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This draft paper is submitted in response to the Office Action dated June 23, 2010 for
which the date for response is September 23, 2010.

A **Listing of Claims** is provided at page 2 of this paper; **Remarks** begin at page 7.

Do not enter MCW 9-2-10

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Previously presented) An isolated polynucleotide comprising an s-ship promoter capable of promoting transcription operably connected to a heterologous nucleic acid sequence, wherein the s-ship promoter comprises nucleotides 54755 to 55810 from SEQ ID NO:1.
- 2.-5. (Canceled)
6. (Previously presented) The isolated polynucleotide of claim 1, wherein the promoter comprises nucleotides 53820 to 55810 from SEQ ID NO:1.
7. (Previously presented) The isolated polynucleotide of claim 6, wherein the promoter comprises nucleotides 51389 to 55810_from SEQ ID NO:1.
8. (Previously presented) The isolated polynucleotide of claim 7, wherein the promoter comprises i) nucleotides 54807 to 61006 but lacking nucleotides 57109 to 57944 or 2) nucleotides 51389 to 55810_from SEQ ID NO:1.
9. (Previously presented) The isolated polynucleotide of claim 1, wherein the promoter comprises nucleotides 49485 to 57111_from SEQ ID NO:1.
10. (Previously presented) The isolated polynucleotide of claim 1, wherein the promoter comprises nucleotides 49485 to 57111 from SEQ ID NO:1.
- 11.-14. (Cancelled)
15. (Previously presented) A nucleic acid comprising a promoter operably attached to a nucleic acid sequence from an s-ship gene or a portion thereof and a marker sequence, wherein the s-ship gene is disrupted by the marker sequence, wherein the promoter comprises nucleotides 54755 to 55810 from SEQ ID NO:1.

16. (Cancelled)

17. (Original) The nucleic acid of claim 15, wherein the promoter is constitutive.

18. (Original) The nucleic acid of claim 15, wherein the promoter is inducible or conditional.

19. (Previously presented) An expression cassette comprising an s-ship promoter operably connected to a heterologous nucleic acid segment, wherein the s-ship promoter comprises nucleotides 54755 to 55810 from SEQ ID NO:1.

20. (Original) The expression cassette of claim 19, wherein the heterologous nucleic acid segment encode a protein.

21. (Original) The expression cassette of claim 20, wherein the nucleic acid segment is a reporter gene.

22. (Original) The expression cassette of claim 21, wherein the reporter gene encodes a gene product that is colorimetric, enzymatic, luminescent, or fluorescent.

23. (Original) The expression cassette of claim 19, wherein the nucleic acid segment encodes a therapeutic or diagnostic gene product.

24.-28. (Canceled)

29. (Previously presented) A vector comprising an s-ship promoter, wherein the s-ship promoter comprises nucleotides 54755 to 55810 from SEQ ID NO:1.

30. (Original) The vector of claim 1, wherein the s-ship promoter is operably attached to a nucleic acid segment.

31. (Original) The vector of claim 30, wherein the nucleic acid segment is all or part of an s-ship coding sequence.

32. (Original) The vector of claim 30, wherein the nucleic acid segment is heterologous.

33. (Original) The vector of claim 29, wherein the vector is a plasmid, YAC, BAC, or virus.
34. (Original) The vector of claim 29, comprised in a pharmaceutically acceptable formulation.
35. (Previously presented) A host cell comprising the expression cassette of claim 19.
36. (Canceled)
37. (Previously presented) The host cell of claim 35, wherein the host cell is an embryonic cell.
38. (Canceled)
39. (Previously presented) The host cell of claim 35, wherein the host cell is a hematopoietic cell.
40. (Previously presented) The host cell of claim 35, wherein the host cell is a stem or progenitor cell.
- 41.-44. (Canceled)
45. (Withdrawn) A mammal having cells comprising an s-ship transgenic sequence.
46. (Withdrawn) The mammal of claim 45, wherein the s-ship transgenic sequence comprises a s-shipl coding sequence flanked by loxP sequences.
47. (Withdrawn) The mammal of claim 46, further comprising a heterologous nucleic acid sequence encoding a Cre recombinase.
48. (Withdrawn) The mammal of claim 47, wherein the nucleic acid sequence encoding the Cre recombinase is under the control of an inducible or conditional promoter.
49. (Canceled)

50. (Withdrawn) A method of screening for a candidate substance that regulates activity of the s-ship1 promoter comprising a step selected from the group consisting of: (a) contacting a nucleic acid comprising an s-ship promoter with an s-ship promoter binding protein and the candidate substance under conditions that allow binding between the protein and the promoter and determining whether the candidate compound modulates the binding between the protein and the promoter; and (b) contacting the candidate substance with a cell comprising the s-ship promoter operably attached to a reporter gene coding for an expression product and assaying for expression of the reporter gene expression product.

51. (Withdrawn) A method for identifying stem cells in a population of cells comprising: (a) administering to cells in the population a nucleic acid comprising an s-ship promoter operably attached to a reporter gene.

52. (Withdrawn) The method of claim 51, wherein the cells are in an organ.

53. (Withdrawn) The method of claim 51, wherein the cell are in an animal.

54. (Withdrawn) The method of claim 51, further comprising sorting cells based on expression of the reporter gene.

55. (Withdrawn) A method for screening for a modulator of cell function comprising: a) transfecting a stem or hematopoietic cell with an expression cassette comprising an s-ship promoter operably attached to a nucleic acid encoding a candidate modulator; and, b) assaying the cell for a cell function, wherein a difference in cell function in the cell as compared to a cell in the absence of the candidate modulator is indicative of a modulator.

56. (Withdrawn) The method of claim 55, wherein the modulator is a candidate therapeutic agent for the treatment of a blood-related disease or condition.

57.-76. (Canceled)

SUMMARY OF ARGUMENTS

I was requested by the Examiner Mr. Wilson to provide a summary of arguments in advance of the Examiner Interview scheduled at 2:00 p.m., September 2, 2010.

Summary of Arguments:

Rejection under 102

The cited reference, Birren (AC 102564 in GenEmbl database), does not anticipate Claims 1, 15, 17-21, 23 and 29-32. The relevant claims recite an isolated polynucleotide comprising a promoter operably connected to a heterologous nucleic acid sequence. In contrast, Birren merely discloses a contig sequence, and nowhere in Birren does it disclose a heterologous nucleic acid sequence. The term "heterologous" is set forth in paragraph [0023] of the specification: "[I]t refers to a nucleic acid sequence that is not normally found in nature (with respect to sequence and position) with the s-ship promoter...."

Rejection under 103

The combination of cited references (Birren in view of Alt or Cooke) does not render claims 1, 15, 17-23, 29-35, 37,39 and 40 obvious. As discussed above, Birren is no more than a contig sequence that provides no contextual information for the sequence. Birren does not indicate that any region of the sequence can be a promoter. Nothing in Alt or Cooke addresses the deficiency of Birren. Consequently, there is no rationale about why any sequence in Birren would be connected to a heterologous nucleic acid sequence.